containing at least one product and one adverse event keyword were collected, de-identified, and standardized using a vernacular to MedDRA dictionary. Posts were classified as resembling an adverse event report (Proto-AEs) or simply discussing a product (Mention). **RESULTS:** There were a total of 1,410,819 posts categorized as Proto-AEs, 265,838 (19%) from Facebook and 1,144,981 (81%) from Twitter. The top 10 products accounted for 940,666 (67%) of the total Proto-AEs in Facebook and Twitter combined. The top 25 accounted for 1,180,040 (84%), the top 50 for 1,285,836 (91%), and the top 100 for 1,245,010 (95%) of the total Proto-AEs. The top 10 products (diphenhydramine, flu vaccine, dextroamphetamine, codeine, morphine, ibuprofen, alprazolam, acetaminophen, oxycodone, and zolpidem) were comprised of six controlled substances, three over-the-counter (OTC) products, and one class of vaccine. Of the top 50 products, controlled substances accounted for 32%, OTC products for 24%, and vaccines for 10%. **CONCLUSIONS:** Review of publically available data over the past two years from two popular social media sites, Facebook and Twitter, offers a high number of potential adverse events (Proto-AEs) for further evaluation. Social listening may be potentially valuable as a supplement to traditional pharmacovigilance practices, particularly for controlled substances, over-the-counter products, and vaccines. These initial findings warrant more research and a closer inspection as to the nature of these posts.

PRM55

HUNTING FOR RANDOMISED CONTROLLED TRIALS (RCTS): A COMPARISON OF SEARCH FILTERS DESIGNED TO IDENTIFY RCTS

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OBJECTIVES: There are a number of search filters designed to identify studies with particular study designs in electronic databases. This study compared three filters for identifying randomised controlled trials (RCTs). **METHODS:** Searches were conducted on 15thJune 2015 in the Ovid MEDLINE and MEDLINE In-process databases using The Cochrane Highly Sensitive Search Strategy for Identifying Randomized Trials in MEDLINE, the SIGN Randomised Controlled Trials MEDLINE filter and the BMJ MEDLINE Randomised Controlled Trial Strategy. Differences were explored by reviewing samples of records uniquely identified by each filter. For comparison, a sample of articles returned by all three filters was also reviewed. To estimate the sensitivity of each filter, the detection of 39 publications of RCTs included in a randomly-selected Cochrane Collaboration systematic literature review (SLR) was tested. **RESULTS:** 476,551 records were identified by all three filters. From a sample of 384 records, 230 were RCTs and 18 were SLRs, meta-analyses or pooled analyses of RCTs. 1,000,716 records were uniquely identified by the Cochrane filter; of 400 records sampled , 0 were RCTs and 3 were SLRs or meta-analyses of RCTs. 500,127 articles were uniquely identified by the SIGN filter; of 386 records sampled, 8 were RCTs and 1 was a meta-analysis of RCTs. 84,938 records were uniquely identified by the BMJ filter; of 400 records sampled, 6 were RCTs and 5 were SLRs or meta-analyses of RCTs. 39/39, 38/39 and 37/39 of the Cochrane review publications were identified by the Cochrane, SIGN and BMJ filters, respectively. The publication missed by the SIGN filter was not the same as the 2 missed by the BMJ filter. **CONCLUSIONS:** All filters failed to identify at least some RCTs, SLRs or meta-analyses of RCTs. Differences between filters, including the publications uniquely identified by each, should be considered when selecting filters for use in literature reviews.

PRM56

INDIRECT TREATMENT COMPARISON (ITC) TO DEMONSTRATE THE UTILITY OF ONCOLITBANK: AN ONCOLOGY LITERATURE REGISTRY

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OBJECTIVES: OncoLitBank is a registry of published oncology trials and Health Technology Assessments aimed to help provide a platform for secondary data analytics in the field of oncology. To demonstrate the utility and functionality of OncoLitBank, we conducted a basic indirect treatment comparison (ITC) between gemcitabine/nab-paclitaxel (GemNpac) and gemcitabine/capecitabine(GemCap) combinations which were each tested against gemcitabine but not against each other for treatment of metastatic pancreatic cancer. **METHODS:** Using OncoLitBank, data for metastatic pancreatic cancer were filtered for treatment-comparator arms of interest by using built-in interactive features. Two phase III randomized controlled trials (RCTs) comparing GemCap vs Gem, while 1 RCT comparing GemNpac vs Gem were included for the ITC. Data on overall response rate (ORR), 1-year survival, overall survival (OS), progression-free survival (PFS), and grade 3-4 adverse events (AEs) were pooled for the 2 RCTs comparing GemCap vs Gem using RevMan 5.0. Pooled risk ratios (RRs) and mean differences (MD) for the 2 studies were derived for dichotomous and continuous outcome variables respectively and compared to the single RCT that evaluated GemNpac vs Gem to derive the ITC RRs and MDs using the Canadian Agency for Drugs and Technologies in Health (CADTH) ITC application which employs Bucher et al. (1997) method. **RESULTS:** The use of OncoLitBank was successful and eliminated the need to conduct a new systematic review to perform the ITC leading to a quick turn-around of tasks at hand. Results demonstrated that GemNpac was not superior to GemCap in ORR, 1-year survival, OS, PFS and grade 3-4 AEs, as no significant differences was detected. **CONCLUSIONS:** OncoLitBank provides users with a robust data platform that can be easily used for systematic reviews, conduct meta-analyses through direct orindirect comparisons, inform economic models, landscape analyses, value dossiers, create target product profiles and value development plans.

PRM57

UTILITY AND METRICS OF NATURAL LANGUAGE PROCESSING ON IDENTIFYING PATIENTS FOR PHARMACOEPIDEMIOLOGIC STUDIES

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OBJECTIVES: Electronic medical records (EMR) are increasingly utilized in clinical practice and research, allowing for more efficient availability of rich patient records. However, most use of EMR is limited to coded, structured, and administrative data, while the vast majority of patient information (e.g. disease subtype, severity, medical device usage, etc.) is tied up in narrative clinical notes. The challenge remains in accessing the information in these patient notes. Historically this has been done via timely and costly manual chart review, but as the amount of EHR data increases exponentially, manual chart review becomes impractical and impossible. Advancements in Natural Language Processing (NLP) have demonstrated promising results in combining the capture of additional clinical note information with the efficiency of modern informatics. The objective of this study is to demonstrate the relevancy and utility of NLP to extract health data from EMR in real-world observational studies. **METHODS:** We conducted a systematic review and meta analysis of performance metrics for five (5) NLP-driven projects involving oncology, inflammation and medical devices ,which had similar protocols and objectives. We assessed and validated the accuracy of NLP algorithms, as well as heterogeneity of accuracy between studies using random effects meta-analysis (represented by I2 value). **RESULTS:** A total of 382,523 patients were identified using NLP among the 5 studies. Accuracy among the studies ranged from 95.2% to 100% (95% CI: 95.1%, 100%), with an I2 value of 95.9% (95% CI: 92.9%, 97.7%). **CONCLUSIONS:** NLP provide a unique opportunity to extract meaningful information from patient-level narrative clinical notes in EMR data sources with high degree of accuracy. This provides additional rich sources of data from narrative clinical notes, that are otherwise not easily available, to support epidemiology and other real-world observational studies.

PRM58

METHOTDOLOGICAL DIFFICULTIES OF COMPLIANCE ANALYSES BASED ON REAL-WORLD DATA

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OBJECTIVES: Regarding compliance analysis numerous ratios can be found in international scientific literature with simpler or more complex methodology. In our analysis we tend to reveal, that choosing an adequate ratio is not sufficient itself, it is essential to know the difficulties and pitfalls of the data management and methodology to the objective assessment of the chosen ratio. The chief aim of our study to demonstrate factors in course of practical examples, which may substantially influence the results and the right conclusions, if these factors are modified. **METHODS:** The analysis is based on prescription refilling's data of database of the Hungarian Health Fund in the field of the following indications: diabetes, COPD, oncology. From the ratios available in scientific literature, the PDC (Proportion of Days Covered) was chosen. The following aspects were considered as influencing factors: patient inclusion criteria (index date, time frame, criteria of refillings); DDD (WHO, SPC or real-world dosage to DOT); Gap (period without medication supply). A basic setting was established to calculate PDC ratio, then after changing each above specified parameters one by one (ceteris paribus), the ratio was recalculated. **RESULTS:** The PDC ratio shows huge variability recalculated by the different values of each parameters. Even more than 20% difference can be observed after modifying the gap (strict 1-day or permissive 30-day), or applying the SPC dosage instead of WHO DDD. In course of modifying the patient inclusion criteria both patient numbers and the ratio also show significant differences. **CONCLUSIONS:** Based on the results it may be concluded, that no general best practice can be observed, all settings have both advantages and limitations. It may be worth choosing the key parameters considering the specialties of each indications in order to draw conclusions as correct as possible with the focus of the original aim of the study.

PRM59

REVIEW OF COMORBIDITY MEASURES TO PREDICT ECONOMIC OUTCOMES IN REAL-LIFE DATABASE STUDIES

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OBJECTIVES: Generic comorbidity measures developed to predict mortality and/or healthcare costs are often used as adjustment covariates in observational studies comparing health expenditures between different therapeutic strategies. The objective of this review is to identify available measures, and assess their performance for prediction of economic outcomes using large longitudinal patient databases. **METHODS:** We conducted a comprehensive literature search in MEDLINE, until April 2015. All methodological papers describing a new comorbidity measure or assessing their ability to predict economic outcomes using administrative data or electronic medical records were selected. We search for additional studies through references lists of selected articles. We extracted information on the conditions for using each index and predictive performance. **RESULTS:** 323 abstracts were identified during the search in MEDLINE and 25 full papers were reviewed. Eleven comorbidity measures and seven comparative studies were found. Four comorbidity measures were single cumulative weighted scores: two were diagnosis-based indexes developed using large administrative health databases and two others were medication-based indexes developed using pharmacy data. Two comorbidity measurement systems consisted in classifying patients in mutually exclusive groups defined based on diagnosis and clinical or economical characteristics. Others were simple counts of diseases. All measures were based on a list of diseases pre-selected by clinicians, except for the Ambulatory Clinical Groups System (ACG). Five measures were adapted for use with ICD-9-CM and ICD-10 classifications. Hierarchical Cost Groups (HCC-CMS) and Quality and Outcome Framework (QOF) showed the highest predictive ability in three comparative studies. ACG was the best predictor in one study and the second one in three other analyses. **CONCLUSIONS:** HCC-CMS and QOF were reported to have the best predictive performance. However most comparative studies included a limited number of comorbidity measures.

The updated version of Charlson Comorbidity Index (CCI), for predicting resource utilisation, was never considered in such studies.

PRM60

THE PEDIATRIC ASTHMA PATIENT REGISTRY IN IMPLEMENTATION OF LONG TERM FOLLOW UP

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OBJECTIVES: The randomized clinical trials (RCT), as gold standard for evidence-based medicine, have a number of shortcomings, and their results do not fully reflect actual clinical practice. In cases where RCTs are difficult to conduct because of ethical or other aspects, data bases of clinical cases - medical registries are used to determine the effectiveness and safety of any medical intervention in long-term observation. Due to heterogeneity of clinical symptoms in different groups of patients with bronchial asthma (BA), to assess the efficacy and safety of treatment of severe persistent uncontrolled asthma in the real clinical practice, the best practice is to use a long-term clinical monitoring. Aim - to create patient registry for children and adolescents with severe persistent uncontrolled BA. **METHODS:** By experts of center in the result of system work software was created. It was shell for management of database of clinical cases – patient registry of children with uncontrolled severe persistent BA, who received Omalizumab as addition to basis therapy. **RESULTS:** The database included information about 64 children (62.5% boys) from 6 to 17 y 11 mo (mean age 12.9 y) with severe persistent uncontrolled BA, who received / receive (31 patients, 70.9% boys) bioengineered treatment (duration of treatment from 1 till 70 mo). During the analyzed period of treatment safety of Omalizumab was confirmed: more than 5384 injections were conducted. Local adverse events were registered at frequency of 1/100 and were manifested as light redness, induration and light edema, were realized in 1-1.5 days after Omalizumab administration. Local allergic reactions such as rash were observed in two patients and were stopped by antihistamines **CONCLUSIONS:** The patient registry will help in solving problems as epidemiological, and in order to achieve optimal endpoints for monitoring and analysis of efficacy and safety of innovative high-tech medications and approaches which have been used previously for long time.

PRM61

THE NATIONWIDE OSMED HEALTH-DB DATABASE. A TOOL TO SUPPORT HEALTHCARE DECISION-MAKING AND REAL-WORLD EVIDENCE GENERATION

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OBJECTIVES: Since 2012, the Italian Medicines Agency (AIFA-Agenzia Italiana del Farmaco), with the cooperation of CliCon, has been providing and updating the OsMed Health-DB Database, a nationwide standardized monitoring system to provide analyses, reports, and trends on appropriateness of medicines' use and medication persistence, to inform decision-makers in order to improve health outcomes and to avoid wasting of health-care resources **METHODS:** The OsMed Health-DB Database has two main components with distinct but complementary functions: a data-warehouse, a repository containing the integrated demographic, pharmaceutical and hospital discharges administrative data kept by Local Health Units (LHUs) and Regional Health Units (RHUs) and a dashboard, a set of performance indicators, with updates scheduled every six months, evaluating the prescription adherence to preset standards of some chronic pathologies at the local, regional, and national level. In 2014, 36 LHUs and 5 RHUs provided data, covering all Italian Regions and the data-warehouse stored information of about 30 million patients (almost the 50.0% of the entire Italian population). **RESULTS:** The 2014 OsMed Report reported the trend of 34 indicators on appropriateness and adherence of 10 chronic diseases: hypertension, hypercholesterolemia, diabetes mellitus, COPD, osteoporosis, depression, ulcers and esophagitis, anemia, psoriasis and rheumatoid arthritis. The average age of the LHU sample resulted 44.0 years versus 43.7 years of the Italian population. The percentage of males resulted 48.5%, in accordance with the national data available. Medication persistence rate for all studied diseases averaged 43.3%, with a range of 13.9% of respiratory system drugs and 62.2% of anti-diabetic drugs. Results will be reported on "National Report on medicines use in Italy" available at AIFA website. **CONCLUSIONS:** Findings from the OsMed Health-DB Database highlighted that the majority of indicators is changing toward appropriateness and adherence. These findings prove that continuous monitoring of appropriateness and adherence is a driver for improving real-world use of medicines.

PRM62

DEVELOPMENT OF AN INTERNATIONAL OBSERVATIONAL STUDY PROGRAMME TO DESCRIBE THE MANAGEMENT AND OUTCOMES OF MILD STROKE AND TRANSIENT ISCHAEMIC ATTACK IN ROUTINE CLINICAL PRACTICE

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OBJECTIVES: Patients with mild stroke or transient ischaemic attack (TIA) are at high risk of recurrent stroke and other cardiovascular events. The Assessment of Real-world Evidence in Stroke/TIA (ARES) programme aims to characterize the management and outcomes of patients with mild stroke/TIA in real-world clinical practice using the most suitable data sources. **METHODS:** In an initial Systematic Understanding of Real-world Evidence (SURE) assessment, suitable data sources (cohorts, registries and databases) were identified and characterized by systematic literature and web searches supplemented with e-mail and telephone contact. Data sources were recommended if they were active, representative, accessible, recorded National Institutes of Health Stroke Scale (NIHSS) scores or ABCD2 scores, and reported health resource utilization, ischaemic events and death during follow-up of at least 90 days (either direct or via linkage). The programme of included studies was finalized with input from principal investigators. **RESULTS:** More than 2900 publications and 300 websites were screened, and 16 registries, 17 cohort studies and 43 databases were reviewed. Nine data sources from seven countries were recommended, of which six complementary sources were included: Get With The Guidelines-Stroke in the USA (an in-hospital database including about 1600 hospitals); National Stroke Registry in China (132 hospitals); Fukuoka Stroke Registry in Japan (seven stroke centres); Clinical Research Centre for Stroke – 5thDivision Registry in South Korea (12 stroke centres); Riks-Stroke in Sweden (all Swedish hospitals admitting patients with acute stroke); and Erlangen Stroke Registry in Germany (Erlanger community). Based on a globally agreed study design concept, protocols for each data source have been developed locally and are now being implemented. **CONCLUSIONS:** The ARES programme will provide global, observational data from contemporary populations with mild stroke/TIA in real-world clinical practice. Studies will be presented individually owing to differences in the nature of the data sources.

PRM63

HEALTH TECHNOLOGY ASSESSMENT NEEDS INFORMATION TECHNOLOGY: THE EXPERIENCE FROM THE FIRST ITALIAN STUDY ON THE DA VINCI SURGICAL ROBOT

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OBJECTIVES: Health Technology Assessment of innovative biomedical devices still requires the effort to introduce dedicated Information Technology tools able to support the implementation of the evaluation process. The aim of the study was to systematize the collection, the management and the analysis of large volumes of multidimensional data in order to optimally conduct an HTA study of emerging technologies. **METHODS:** We designed a relational database, subsequently we developed and implemented a centralized, web-based user-friendly data entry for Case Report Form (CRF) data collection. (i) The development of User Interface (UI), (ii) data anonymization, (iii) differentiate accesses, (iv) automated quality control checks for data entry, (v) appropriate system tables to make data entry uniform, and (vi) the possibility of creating final reports were addressed. In the data extraction phase, we used MySQL computer languages and combined PHP and HTML codes. Knowledge Discovery in Data process was implemented with different software and programming languages for automation of the data collection, extraction and analysis. **RESULTS:** The IT tools have been applied to the first multicenter prospective Italian study of HTA on the da Vinci surgical system, obtaining meaningful end points in terms of costs and clinical outcomes. The study involved the enrolment of 699 patients from the 8 Italian Teaching Hospitals in the period 2011-2014. Patients were enrolled and prospectively evaluated from the preoperative work-up till six months after the discharge. **CONCLUSIONS:** The IT tools developed allow researchers to more efficiently and effectively manage large volumes of various source of HTA data, enhancing data quality from storage to processing. The database design could be empowered and readjusted for other HTA studies in near future and the entire approach generalized. In the immature field of HTA of innovative biomedical devices, this example of application could promote the automation of the implementation process of HTA.

PRM64

MANAGEMENT OF SOFT TISSUE SARCOMA (STS) IN FRANCE - A RETROSPECTIVE ANALYSIS OF THE FRENCH CLINICAL BIOLOGICAL SARCOMA DATABASE (GSF-GETO)

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OBJECTIVES: The primary objective is to describe how patients with advanced STS are managed in France. The secondary objectives are to describe the epidemiological characteristics, the diagnostic procedures as well as the therapeutic strategy for the management of patients with STS. **METHODS:** This observational, retrospective and national study will use the patient databases of the European CONTICANET "CONnective TIssue Cancer NETwork" network and of the French networks: RRePS and NetSarc(Pathological and Clinical Reference Networks for Soft Tissues and Visceral Sarcomas) . All the data collected in these networks and compiled in the "Sarcoma clinicobiological database" will allow good national representativity of STS. The study period was defined to reflect the current situation in terms of diagnosis and disease management in France. **RESULTS:** The European database currently contains data from 12,485 patients (pts) registered by the French Sarcoma Group centers with 9,736 soft tissues and visceral sarcomas. Data from STS patients, who were diagnosed between 2012 and 2013, will be extracted from the Conticabase database. Part of these data will be "chained" with the shared database from the French networks RRePS (24,000 pts) and NetSarc (28,000 pts). Results are expected at the end of 2015. **CONCLUSIONS:** This pharmacoepidemiological study shows how useful high-quality medical databases are to study rare diseases and their management in real life. This study is carried out as part of a public/private partnership.

PRM65

THE REMOTE MONITORING TECHNOLOGIES IN THE PATIENT RISK MANAGEMENT

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OBJECTIVES: Due to high prevalence of socially significant chronic diseases among children the introduction of information technologies in the process of interaction between doctor and patient is important. The aim: to analyze the prospects of the development of remote monitoring systems, to identify their shortcomings and to propose solutions. **METHODS:** The review had included 36 publications, 1 meta-analysis concerning telemedicine from 2001 to 2014 y. In the evaluated studies the following questions were explored: • research of social and economic aspects of